

**WHAT IS CLAIMED IS:**

1. A method for designing a pharmaceutical composition for reducing the risk of ovarian cancer comprising an agent, said method comprising obtaining information on said agent's ability to induce biologic effect to regulate TGF- $\beta$  expression in the ovarian epithelium and selecting said agent after consideration of such information.
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2. The method of claim 1 wherein said TGF- $\beta$  expression is expression of TGF- $\beta$  3 or TGF- $\beta$  2.
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3. The method of claim 1 wherein said TGF- $\beta$  expression is expression of TGF- $\beta$  1.
4. The method of claim 1 wherein comprising testing said agent for its ability to regulate TGF- $\beta$  expression in the ovarian epithelium.
5. A hormone replacement therapy regimen comprising the composition made by the method of claim 1.
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6. A contraceptive formulation comprising the composition made by the method of claim 1.
7. A regimen comprising the composition made by the method of claim 1 and at least one hormone selected from the group consisting of estrogens and progestins, wherein said agent can be the same as or different from said hormone.
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8. The method of claim 1 wherein said agent is a non-estrogen and non-progestin compound.
9. A pharmaceutical regimen comprising one or more agents, said regimen made by the process of considering of the ability of said one or more agents to upregulate expression of one or more TGF- $\beta$  isoforms in the ovarian epithelium, considering the 25 ability of said one or more agents to downregulate expression of one or more other TGF-

β isoforms in the ovarian epithelium, and selecting said one or more agents after such consideration).

10. The regimen of claim 9 wherein said regimen comprises a daily dosage of a composition which includes said one or more agents.

5 11. The regimen of claim 9 wherein said one or more agents comprises a first agent and a second agent wherein said first agent has the ability to upregulate expression of one or more TGF-β isoforms in the ovarian epithelium and said second agent has the ability to downregulate expression of one or more other TGF-β isoforms in the ovarian epithelium.

10 12. The regimen of claim 9 wherein said regimen includes a single unit dosage comprising said first agent and said second agent.

15 13. The regimen of 9 including a pulse of periodic dosages wherein said one or more one or more agents upregulate expression of one or more TGF-β isoforms in the ovarian epithelium to a greater extent during one portion of the regimen than during another portion of the regimen.

14. The regimen of 9 including a pulse of periodic dosages wherein said one or more one or more agents downregulate expression of one or more TGF-β isoforms in the ovarian epithelium to a greater extent during one portion of the regimen than during another portion of the regimen.

20 15. A hormone replacement therapy regimen comprising the composition of claim 9.

16. A contraceptive formulation comprising the composition of claim 9.

25 17. The composition of claim 9 wherein said one or more upregulated TGF-β isoforms comprises an isoform selected from the group consisting of TGF-β 3 and TGF-β 2.

18. The composition of claim 9 wherein said one or more downregulated TGF- $\beta$  isoforms comprises TGF- $\beta$  1.

19. A pharmaceutical composition comprising one or more agents, said composition made by the process of selecting said one or more agents based on the ability of said one or more agents to alter the ratio of one or more TGF- $\beta$  isoforms in the ovarian epithelium to one or more other TGF- $\beta$  isoforms in the ovarian epithelium.  
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20. A hormone replacement therapy regimen comprising the composition of claim 19.

21. A contraceptive formulation comprising the composition of claim 19.

10 22. A regimen comprising the composition of claim 19 and at least hormone selected from the group consisting of estrogens and progestins.

23. The composition of claim 19 wherein at least one of said one or more agents is a non-estrogen and non-progestin compound.

15 24. A method for designing a pharmacological composition comprising treating ovarian epithelial cells with a first progestin; testing said progestin-treated cells using microarray technology; identifying one or more biomarkers relevant to ovarian epithelial cancer prevention based on the expression altered by progestin action; treating normal ovarian epithelium cells with one or more candidate pharmacological agents; testing said candidate agent-treated cells with microarray technology for alteration of said 20 one or more surrogate biomarkers; and selecting said candidate agents based on such tests.

25 25. The method of claim 24 further comprising subsequently selling and/or prescribing the resulting composition and/or regimen for administration to a female subject in need thereof.

26. The method of claim 24 further comprising administering said regimen to a post-menopausal female subject.  
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27. The method of claim 24 further comprising administering said regimen to a peri-menopausal female subject.

28. The method of claim 24 further comprising administering said regimen to a pre-menopausal female subject.

5 29. The method of claim 24 further comprising selecting a second agent based on consideration of said second agent's ability to upregulate expression of one or more TGF- $\beta$  isoforms in the ovarian epithelium.

30. The method of claim 24 wherein said one or more candidate agents include a second progestin.

10 31. The method of claim 24 wherein said one or more candidate agents include a non-progestin agent.

32. A regimen comprising the composition made by the method of claim 24 and at least one hormone selected from the group consisting of estrogens and progestins, wherein said agent can be the same as or different from said hormone.

15 33. The method of claim 24 wherein said progestin is levonorgestrel.